UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No: 03-10643
THIS DOCUMENT RELATES TO: *City of New York* v. *Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk* v. *Abbott Labs., et al.* (E.D.N.Y. No. 03-CV-229) *County of Westchester* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess* v. *Abbott Labs., et al*. (S.D.N.Y. No. 05-CV-06458) *County of Putnam* v. *Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00425)	Judge Patti B. Saris

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DEFENDANTS' RESPONSE TO THE SUPPLEMENTAL BRIEF OF THE UNITED STATES ON THE FEDERAL UPPER LIMIT

County of Warren v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. *Abbott Labs. et al.*)
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County of Fulton v. *Abbott Labs., et al.*)
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County of Jefferson v. *Abbott Labs., et al.*)
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County of Lewis v. *Abbott Labs., et al.*)
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County of Chautauqua v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06231))
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County of Genesee v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06206))
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County of Monroe v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. *Abbott Labs., et al.*)
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County of Niagara v. *Abbott Labs., et al.*)
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County of Seneca v. *Abbott Labs., et al.*)
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County of Orleans v. *Abbott Labs., et al.*)
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County of Schuyler v. *Abbott Labs, et al.*)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. *Abbott Labs., et al.*)
(E.D.N.Y. No. 04-CV-5126))

PRELIMINARY STATEMENT

In framing the issue that it would need to decide on summary judgment, this Court asked whether plaintiffs could prove that "defendants submitted false or inflated *published* prices which, if truthful, would likely have affected the FUL"? *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 402, 405 (D. Mass. 2007) (emphasis in original). On the record before this Court, plaintiffs cannot make such a showing. There is nothing in the record to contradict the key points that defendants developed through the discovery of CMS and that are made in Dr. Addanki's affidavits: (1) For every generic drug at issue, there are actual lower published prices that did not in fact result in CMS's setting a lower FUL, and (2) there is no mechanical rule that systematically explains how, when, or why CMS chose to deviate from the terms of the FUL regulation.

In sharp contrast to its 2007 filing, the United States Department of Justice ("DOJ") now acknowledges, as the CMS witnesses testified more than a year ago, that ***"discretion was exercised"*** in setting FULs "to ensure beneficiary access to the drugs while still also achieving cost savings for the Medicaid program" and there ***"has not been a steadfast rule"*** applied in exercising this discretion. Supplemental Brief of the United States on the Federal Upper Limit (hereinafter, "Supp. Br.") at 3 (emphasis added).[1] Accordingly, it is impossible for plaintiffs to show, long after the fact, that, had defendants published lower prices, those lower prices would have resulted in CMS's setting lower FULs – much less, which lower prices might have triggered a lower FUL or what the resulting FUL might have been. Put differently, plaintiffs

[1] *See also* Supp. Br. at 1 (acknowledging that the CMS "deposition testimony and documentary evidence has shown that certain statements in the United States' [2007] brief were incomplete, if not inaccurate"); *id.* at 2 (acknowledging that the 2007 brief provided "an incomplete description of the mechanics of the FUL-setting process").

cannot meet their burden of proving liability, causation, or damages as to their so-called "FUL fraud" claims, and summary judgment should enter in defendants' favor as to those claims.

BRIEF RESPONSE

A. The Department of Justice's Second *Amicus* Brief Confirms that Defendants Are Entitled to the Entry of Summary Judgment in Their Favor.

DOJ's supplemental submission regarding FULs confirms the undisputed material facts entitling defendants to summary judgment in at least three significant regards:

First, the submission confirms that the "FUL-setting process" is a manually-intensive (not "mechanical" or "automated") process during which substantial discretion is exercised – not that this fact could be legitimately denied in light of the discovery record in this case. As the brief explains, manual intervention occurs at, at least, two different points in the process of setting a FUL: first, following an (admittedly) "imperfect" matching process, CMS typically "manually review[s] and reassign[s]" unmatched products to particular product groups – although the brief candidly acknowledges that this is "a tedious task that is not always performed with perfect regularity." Supp. Br. at 7. Then, as the CMS witnesses testified, after the FULs computer system produces its output, "[t]he FULs analyst manually reviews the FULs System output to ensure that the final FUL is consistent with CMS's program objectives." *Id.* at 8. For prices deemed "important to the determination of a FUL," the brief says the "FULs analyst typically contacts" (but not always) "the manufacturer to verify that the prices are valid and that the products are widely available in the market." *Id.* Moreover, the brief explains that, when CMS exercises discretion, it does so "to ensure beneficiary access to the drugs" by disregarding

lower published prices. *Id.* at 3. In short, if DOJ's 2007 submission had candidly acknowledged these facts, much (if not all) of the CMS discovery would not have been necessary.[2]

Second, DOJ's supplemental submission confirms what the documents that CMS produced plainly show and what the CMS witness clearly testified – that is, that the FULs System identified actual existing lower published prices that CMS chose to disregard in setting FULs. *See* Supp. Br. at 3 (acknowledging that "CMS might reject the lowest price (treating it, in effect, as an outlier) and instead calculate the FUL based on the next higher price"). Defendants attached to their opening brief four printouts from the FULs System showing CMS exercising its discretion to disregard lower published prices, *see* Defs.' Mem. at Ex. A (Dkt. No. 6084), and reattach those same printouts to this submission. *See* Ex. A.[3] Nothing in the record or Ms. Gaston's two supplemental declarations undermines this simple, undisputed, and dispositive fact. Indeed, Ms. Gaston's Second Declaration (hereinafter "2nd Gaston Decl.") (Dkt. No. 6693-3) treats two of the FULs reflected in these printouts (her Second Declaration does not address the metoprolol and cefadroxil FULs) and confirms, after extensive research and analysis, that there were at least three existing, valid prices that the FULs System had identified and that the FULs analyst had available to her at the time she was setting the FUL, and that CMS decided to disregard those existing lower published prices and set a higher FUL. *Id.* at Att. E and H. Moreover, as DOJ's brief points out, there would have been more of these FULs Systems printouts had CMS taken steps to preserve them. However, despite the pendency of many AWP lawsuits, apparently prior to 2001, the FULs system did not "preserve[] a 'snapshot' of the data

[2] Apparently, prior to 1999, the process of setting FULs entailed even "considerably more manual review." Decl. of Dona Coffman, ¶ 19 (Dkt. No. 6693-2) (hereinafter, "Coffman Decl.").

[3] *See also* L.R. 56.1 Stmt. of Undisputed Material Facts Supporting Defs.' Jt. Mot. for Summary Judgment (Dkt. No. 6054), at ¶¶ 17-20 and 23-24 (collecting the deposition testimony regarding these FULs printouts).

in the FULs System database" and no effort was made to preserve that data.[4] Supp. Br. at 8 and nn.8-9 ("Print-outs before about 2001 have not been located.").

Third, and perhaps most importantly, DOJ's brief concedes that Ms. Gaston's *post-hoc* "three WAC rule-of-thumb" is just that. It is not a rule at all, and certainly not one that has been steadfastly followed. *See* Supp. Br. at 3 (reciting the "three WAC rule-of-thumb" and then conceding, "[t]his has not been a steadfast rule, however"). As the brief and the second Gaston declaration highlight, the practices described therein were followed some of the time, but not always, and there is no record as to precisely when or why these practices were followed in one case, but not in other similar circumstance. *See* Supp. Br. at 9 (noting that exclusion codes were assigned "typically" based on analyst communications with manufacturers); 2nd Gaston Decl. at ¶ 8 (noting that she "occasionally" assigned unmatched NDCs to a Product Group and "rarely" (although not never) assigned an NDC to a different product group or excluded it altogether); *id.* at ¶ 10 (noting that she would "normally contact" a manufacturer if she noted conflicting prices).

To the extent that DOJ's brief seeks to suggest that CMS followed ***any*** mechanical or systematic rule in setting FULs, defendants submit that the brief is equally as misleading as DOJ's 2007 submission.[5] As Mr. Fauci candidly acknowledged on behalf of DOJ, when first confronted with this Court's request that DOJ make a supplemental submission regarding FULs: "[I]t's probably obvious that the FUL-setting process was not mechanistic in any way." 7/8/09

[4] Even post-2001, the brief concedes that the record-keeping tool created in 2001 "is imperfect in certain respects" – a fact confirmed by the paucity of FULs System printouts produced by CMS in discovery. *See id.* at n.9.

[5] Any suggestion that the "FULs analyst [had] limited ability to affect the output of the FULs System" – while perhaps truthful on its face – is disingenuous and potentially even more misleading. *See* Supp. Br. at 8. While the FULs analyst may not have been able to affect the system output, as Ms. Coffman avers, the FULs analyst had almost unfettered discretion to affect the FUL that CMS set. *See* Decl. of Dona Coffman, at ¶ 17 (averring that "[t]he analyst c[ould] override the automatic calculation of the FUL and insert a different FUL," could "assign a particular NDC to a Product Group or remove an NDC from a Product Group," or exclude a particular NDC altogether).

Hr'g. Tr. at 93:16-18.[6] This was the truth then and remains the truth today. This fact standing alone entitles defendants to summary judgment. *See, e.g., id.* at 92:7-8 ("THE COURT: It just seems like any damages figure is speculative at this point.").[7] However, the reasons for allowing defendants' motion for summary judgment go far beyond that and, taken together, they are even more compelling.

In attacking Dr. Addanki's analysis, DOJ erects a "straw man" and then succeeds only in proving Dr. Addanki's point. As Dr. Addanki stated clearly in the affidavit that he submitted in support of defendants' motion for summary judgment, and as he told the Court during the tutorial, the point of his analysis was to show that, "CMS did not follow any simple rule, or, indeed, any discernable pattern, in setting FULs but, rather, exercised its discretion on a case-by-case basis, almost always ignoring lower published prices, [which] flatly contradicts the hypothesis that lower published prices would have led to lower FULs." 5/15/09 Aff. of Dr. Sumanth Addanki, at ¶ 15 (Dkt. No. 6056).[8] Dr. Addanki's primary objective was never to replicate precisely CMS's methodology, as Ms. Gaston's Second Declarations seems to suggest, but rather to examine the question of whether plaintiffs' theory of "FUL fraud" makes any

[6] *See more generally* 7/8/09 Hr'g. Tr. at 93:3-18 (Mr. Fauci acknowledging that DOJ's 2007 brief was "not consistent with Ms. Gaston's or Ms. Sexton's testimony" and that it is "obvious that the FUL-setting process was not mechanistic in any way" in response to remarks by this Court that the 2007 brief created a "misimpression" and was "just wrong.")

[7] *See also id.* at 28:4-14 ("THE COURT: Well, we know they're flat out violating this regulation. So assume you're right that they do that systematically. . . . So what you're saying here is, you can't really predict if everybody had truthfully reported their WACs so that that was the lowest published price . . . – you couldn't predict what they [referring to CMS] would do with that."); 31:3-7 ("THE COURT: You're just simply saying it's not clear why they would pick any particular price . . . , and there's no regulation or policy or practice that would help us?"); 61:6-7 ("THE COURT: What if there's no possible way of figuring out damages?"); 61:24-62:3 (acknowledging in response to the Court's questioning that plaintiffs "have not sued everybody" who "had a therapeutic equivalent with [an allegedly] false WAC").

[8] *Id.* at ¶ 8 ("FULs are almost impossible to predict and certainly impossible for a manufacturer to manipulate in any meaningful way."); 7/8/09 Hr'g. Tr. at 31:22-25 (CMS "deviate[s] from this very simple rule of 150 percent of the lowest published price very, very systematically, in the sense that the deviation happens a lot. The manner in which they deviate is extremely variable.").

economic sense, in light of the facts and the discovery record that exists in this case. *Id.* at ¶ 2 (describing the scope of Dr. Addanki's assignment). Nor could he have been expected to do so.

As the declarations filed along with DOJ's submission reveal for the first time, in setting FULs, among other things, CMS created its own product groupings, it engaged in a self-described "fuzzy" matching process, it eliminated all unit-dose products (although this makes no sense since one of the products at issue is the albuterol unit dose) and, "for historic reasons unknown today, the data received from Medi-Span does not include WAC price data" (despite the fact that Medi-Span is one of the three national pricing compendia that the regulation requires CMS to use and CMS witnesses have said that CMS based FULs on WACs, and not AWPs). *See* Supp. Br. at 6; *see also* Coffman Decl., ¶¶ 9-10 and 14-15 and n.2. None of this, of course, is apparent from the face of the FUL regulation, nor was any of it described by the CMS witnesses when they were asked to describe how they set FULs. Thus, neither Dr. Addanki nor anyone else outside of CMS for that matter, including the defendant manufacturers, could have known – let alone replicated – these steps.

Thus, when Dr. Addanki's analysis is placed in a proper context, it quickly becomes clear that Ms. Gaston's Second Declaration says nothing that undermines the primary conclusions that Dr. Addanki reaches – *i.e.*, that for sound policy reasons, CMS chose not to follow the simple rule set forth in the FUL regulation and "[t]he manner in which [CMS] deviate[s] is extremely variable." 7/8/09 Hr'g. Tr. at 31:24-25. In fact, consistent with the conclusions that Dr. Addanki reaches and far from manufacturing any disputed issue of material fact, Ms. Gaston's Second Declaration actually proves Dr. Addanki's primary points. Setting aside the fact that Ms. Gaston's analysis is incomplete (Ms. Gaston's Second Declaration addresses only 13 of the 31

FULs at issue and only five of the nine generic drugs chosen for targeted discovery),[9] Ms. Gaston's Second Declaration examines:

- ***Six FULs for which she concludes that, if the lower published prices that Dr. Addanki identifies were found to be "available and valid" at the time CMS set the FUL, CMS would have set a lower FUL than the one it set***. For each of these FULs, Ms. Gaston goes on to speculate that the prices Dr. Addanki identifies must not have been available to CMS – otherwise, CMS would have used them. However, in each case, Ms. Gaston must concede that, "There is no hard-copy documentation indicating the basis for th[e] FUL." *See, e.g.*, 2nd Gaston Decl., App. C, at ¶ 1. Moreover, nothing in Ms. Gaston's Second Declaration disputes that the prices Dr. Addanki identifies were identified by applying the terms of the FUL regulation as written. Furthermore, she must admit (and does) that the lower published prices that she seeks to dismiss through her speculation would not have been disqualified on the basis of being outdated, obsolete, for a unit dose form of the product, or from a manufacturer who did not have a valid rebate agreement in effect at the time the FUL was set. *See, e.g., id.* at ¶ 3 ("The Labeler Agreements file indicates this labeler did have an effective Rebate Agreement at the time.") Thus, as to these prices, all she can do is speculate that, for some unspecified reason, they were removed from consideration. *See, e.g., id.* ("I ***suspect*** that the FULs System logic excluded this NDC from the database for some" (unspecified) "reason dictated by the FULs System program logic" but "If the product was not excluded by the FULs System logic, the manufacturer ***may have been contacted"*** (although she cannot say absent the non-existent documentation whether or not this happened) "and [the] product determined to have been unavailable or the price not valid.") (emphasis added). Put differently, there is simply no evidence in the record to explain why any of these existing lower published prices were not used by CMS to set a lower FUL. *See also* 2nd Gaston Decl. at App. A-B, D & F-G. For a more detailed treatment of Ms. Gaston's rank speculation, please see Exhibit B hereto.
- ***Four additional FULs in which the "3 WAC rule of thumb" clearly wasn't followed.*** In particular, for each of the albuterol FULs that Ms. Gaston examines, her analysis shows there were not three WACs (including the one that set the FUL) that were less than the FUL that CMS set. Attachment I, for example, illustrates that the FUL set for the 90 MCG albuterol inhaler in October 1, 1997, was based on the lowest published WAC and only the WAC on which the FUL was based was lower than the FUL that was set by CMS. *See* 2nd Gaston Decl. at Att. I; *see also id.* at App. J and K (setting forth similar illustrations). As to the FUL set for the .083% albuterol solution (the albuterol unit dose product) in January 2002, Ms. Gaston's Second Declaration expressly acknowledges that "CMS chose not to use a higher WAC to calculate the FUL ***in this situation***" (roughly translated, it did not follow the "3 WAC rule-of-thumb") "because of concerns raised from an Office of Inspector General report on albuterol relating to inflated published prices." *Id.* at Att. L, ¶ 2 (emphasis added).

[9] Ms. Gaston claims "[t]ime constraints . . . made it impractical" to evaluate all of Dr. Addanki's slide. *See* 2nd Gaston Decl., at ¶ 4. Defendants would only note that the oral argument on FUL summary judgment motions was held more than five months ago on July 8, 2009.

In short, using Ms. Gaston's own analysis, the supposed "rules" and FULs System "logic" explains only three of the thirteen (23%) FULs that Ms. Gaston analyzes in her Second Declaration, and she cannot explain even those on the basis of CMS's written FUL regulation. The rest are indisputably the product of an *ad hoc* exercise of discretion – for sound policy reasons – but one that mandates the entry of summary judgment in defendants' favor. Having routinely ignored actual, existing lower published prices, plaintiffs cannot now establish that, had defendants published other lower prices, CMS would have used those prices to set FULs. Accordingly, defendants are entitled to the entry of summary judgment in their favor.

B. If the Court Is Not Inclined to Enter Summary Judgment in Defendants' Favor, then It Should Re-open the Record for Further Discovery.

Notwithstanding the foregoing, if the Court is not inclined to grant defendants' Motion for Summary Judgment, then defendants respectfully request that the Court re-open FUL discovery and grant them an opportunity to re-depose Sue Gaston, depose Dona Coffman, Cindy Bergen (about whose work Ms. Gaston often speculates) and Peter Rodler, and take such other depositions as might be necessary and appropriate to more completely develop the discovery record. Defendants would also request an order compelling the United States Department of Justice to produce the computer code used to run the FULs System. It is fundamentally unfair for CMS/DOJ to deny defendants' requests for, *inter alia*, the code that runs the FULs System and other FUL-related discovery, *see* Ex. C hereto (e-mails and letters requesting the FULs System code and other FUL-related discovery and CMS's responses), hiding behind *Touhy* and claims of burden, only then to furnish the very same information that defendants sought to plaintiffs, after the close of discovery, so that they can use it in an effort to defeat summary judgment by creating the appearance of some non-existent disputed issue of material fact. Although, on the factual record before this Court, defendants are clearly entitled to the entry of

summary judgment in their favor, if the Court disagrees, at a minimum, the Court should re-open the record and permit defendants additional FUL-related discovery.

C. The DOJ Supplemental Brief and Affidavits Do Not Address the Fact the "FUL Fraud" Theory Is Fundamentally Inconsistent with CMS's AMP Methodology.

The DOJ's second *amicus* brief was not filed in a vacuum. As this Court is aware, DOJ was present at argument on defendants' motion and knows that the essence of the "FUL fraud" theory is an argument by plaintiffs that published WACs should have been some form of net prices. Thus, what is notably absent about DOJ's submission is that it – in no way – addresses this fundamental underpinning. That omission has the potential to enable some basic assumptions to persist that are contrary to the eighteen years' of history of calculation of AMP under the Manufacturers' Rebate Agreement introduced in 1991 pursuant to OBRA 90.

CMS and OIG published definitions, guidance and comments over the entire eighteen-year period that clearly distinguish between "gross prices" – *i.e.*, catalog or list prices – and "net prices" – *i.e.*, AMP. In this context, the definition of WAC in 2003 as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data," 42 U.S.C. §1395w-3a(c)(6)(B), confirms a key fact that renders plaintiffs' FUL Fraud theory an impossibility: For CMS purposes, published WACs have always been the "gross" or invoice prices from which rebates and other price concessions were deducted to arrive at AMP or "net" price. **Thus, at every point in time at which CMS set FULs based on published WACs (or Direct Prices), it knew that lower, "net" prices were available in the marketplace.** In other words, even had CMS been setting FULs based on lowest published WACs (or Direct Prices) – and it decidedly was not – it could not possibly have

done so in the belief that such prices were manufacturers' lowest selling prices. Simply put, CMS is trying to pound a square peg into a round hole and, the more it pounds, the less sense its arguments make.

The undisputed – and indisputable – public record relating to the definition and calculation of AMP makes this conclusion inescapable. The foundation for understanding the methodology for computing AMP is OBRA 90 and its progeny, the Medicaid Rebate Agreement.[10] The Medicaid Rebate Agreement defines AMP as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade . . . . Specifically, it is calculated as Net Sales divided by number of units sold." Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer § I(a), *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf (hereinafter, "Rebate Agreement"). "Net Sales" is defined in the Medicaid Rebate Agreement as "quarterly gross sales revenue *less* cash discounts allowed and all other price reductions . . . which reduce the actual price paid." *Id.* § I(p) (emphasis added). Thus, from the inception of the Medicaid Rebate Program, the Rebate Agreement itself has recognized the difference between "gross sales" – i.e., the "total of all sales at invoice prices, not reduced by discounts, allowances, returns, commissions or other adjustments," *Black's Law Dictionary* 486 (abridged 6th ed.) – and lower "net sales" that are only derived after deductions made in accordance with guidance by CMS. This distinction is inevitably inconsistent with any argument that, for CMS/Medicaid, WAC can be anything other than an undiscounted list price.

[10] *See* Office of the Inspector General, Department of Health & Human Services, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program*, at 2, *available at* http://www.oig.hhs.gov/oas/reports/region6/69100092.pdf (hereinafter "1992 OIG Report").

That this distinction between gross sales and net sales makes it impossible for HCFA/CMS ever to have considered WAC to be a net price is reflected in the 1992 OIG report entitled *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program*. *See* Office of the Inspector General, Department of Health & Human Services, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug manufacturers to Better Implement the Program*, *available at* http://www.oig.hhs.gov/oas/reports/region6/69100092.pdf (hereinafter "1992 OIG Report"). While HCFA took the position that the drug rebate law and rebate agreements were sufficient to provide a methodology for computing AMP, OIG disagreed. As described by OIG, the purpose of the report was to provide HCFA "with the results of our review of selected drug manufacturers' methods used to determine average manufacturer prices (AMP) and best prices under the Medicaid drug rebate program" and its conclusions that:

> Although we found that best price determinations were acceptable, manufacturers' calculations of AMP were inconsistent. We found major variations in the methods used by manufacturers to determine AMP. For example: (1) one manufacturer based the calculations on gross sales to wholesalers, (2) two manufacturers based the calculations on net sales to wholesalers, and (3) one manufacturer specifically identified sales at the retail level for its calculations. **These variations occurred because HCFA has not provided sufficiently detailed instruction to manufacturers on acceptable methods for calculating AMP for drugs distributed to retail pharmacies.**

Id. at 1. The differences between "gross sales" and "net sales" played a key role in OIG's conclusions. OIG analyzed the process and effects involved in the different methods of AMP calculation. With regard to the manufacturer that used its gross selling price to wholesalers with no adjustments to sales in determining its AMPs, OIG observed: "In the interest of simplicity, this manufacturer apparently did not attempt to identify its products actually distributed to the retail pharmacy class of trade or adjust for chargebacks." *Id.* at 6. As OIG further noted, "[t]he

HCFA is opposed to this method for identifying AMPs" even though this method results in a higher AMP and a higher rebate, because it is based on an undiscounted price. *Id.* at 7. OIG urged HCFA to "reevaluate its position":

> A manufacturer who is willing to provide AMPs, based upon catalog prices as a concession against the burden and costs of calculating actual AMPs, is in effect providing the Medicaid program with the highest AMPs and rebate payments possible. Additionally, the manufacturer who provided the AMPs based on a gross price which is the same for all wholesalers, before considering adjustment for chargeback sales, is providing the Medicaid program with AMPs which seem to be accurate even though it did not specifically identify the sales to the retail class of trade.

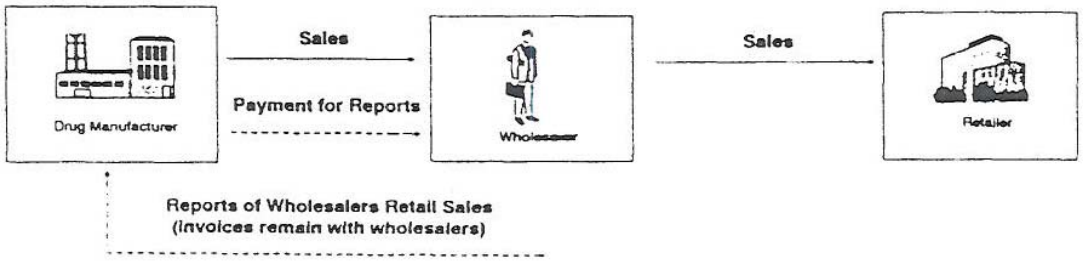
Id. Thus, in describing a "gross sales price" or a catalog price" as a price "which is the same for all wholesalers, before considering adjustment," OIG effectively described a "list price." This is entirely consistent with the definition of WAC in the MMA as "the manufacturer's list price . . . , not including prompt pay or other discounts, rebates or reductions in price, . . . , as reported in wholesale price guides or other publications of drug or biological pricing data." 42 U.S.C. §1395w-3a(c)(6)(B). Simply put, since its inception, AMP has had a methodological framework in which "gross sales price" is the list price (WAC) and AMP is a "net sales price" calculated by subtracting specified "cash discounts allowed and all other price reductions . . . which reduce the actual price paid." Rebate Agreement § I(p). As CMS concedes that FULs are generally based on published WACs (or Direct Prices), *see* Br. of the United States on the Federal Upper Limit, at 4 (Dkt. No. 4413), it follows that CMS has always known that lower "net" prices existed and could not possibly have believed that it was setting FULs based on "net" prices.

Interestingly, CMS, in effect, explained this in the Deficit Reduction Act of 2005, when, in response to a comment requesting that CMS "clarify"[11] the "Definition of Net Sales," CMS stated:

[11] *See* 72 Fed. Reg. 39142-01, 39164 (July 17, 2007) (responding to comment by indicating that HHS "appreciate[s] the support for this provision and have retained this requirement in this final rule at § 447.504(d)").

> Net sales should be calculated as gross sales less cash discounts allowed and other price reductions (other than rebates or price reductions excluded by the statute or regulations) which reduce the amount received by the manufacturer. **We have defined AMP to center on the concept of a transaction, such that any given transaction includes both the "sale" and any discounts, rebates or other price concessions associated with that sale.** In certain instances, the statute or regulations specifically exclude from the calculation of AMP either certain portions of a transaction or entire transactions with certain entities. **Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions**. In the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculations, consistent with the general requirements and intent of the Act, Federal regulations and customary business practices.

42 C.F.R. § 447.504. This view that the beginning point for calculation of AMP is the initial "sale" as invoiced was not new. In the 1992 OIG report, OIG addressed AMP calculations based on "Specific Identification of Retail Sales" and made it clear that: "We consider the sales invoice to be the basic record of sale and should be required as proof of sale for audit purposes." In so doing, OIG provided the following diagram identifying two levels of "sales" that would need to be documented by invoices for audit purposes – sales by the manufacturer and sales by the wholesaler:



1992 OIG Report, at 9.[12] Notably, OIG further observed that: "Officials at this manufacturer agreed with our interpretation that the sales invoice was needed for proof of the sale" and that, while the manufacturer did not have access to the wholesaler's invoices, "[t]he manufacturer did

[12] Again, as this example makes clear, the invoice supporting the sale is the basis for calculating "gross sales" and it is undisputed that such invoices generally reflect list prices such as WAC (or Direct Price). As clearly set forth by CMS in the DRA, "net prices" are arrived at by matching gross sales (i.e., sales at WAC) with their associated price concessions. Thus, it is simply impossible for CMS to have set FULs based on published WACs (or Direct Prices) without knowing that lower "net prices" were available in the marketplace and the foundation for the FUL-Fraud theory – that CMS believed published prices to be net prices – is simply nonexistent.

provide sales invoices supporting each transaction sampled from their direct sales to the retail pharmacy class of trade." *Id.* at 10.

Any effort by plaintiffs to explain away the clear import of CMS and OIG's own words by arguing that the 2005 definition of WAC in the MMA reflected a change in its meaning must fail. WAC has been an industry term for decades – in fact, since long before the chargeback system that is a key element of "net prices" even existed. That it was commonly understood to be a list price is reflected in CMS's own method for calculating AMP. Had that not been the case, a change in its definition would clearly have called for guidance from CMS at the time of the passage of the MMA and such a change would have been reflected in the extensive discussion and commentary on the history of AMP reflected in the DRA, two years after the definition of WAC in the MMA. No such guidance or discussion exists. In the words of Sherlock Holmes, this is a "curious incident" of the dog that did not bark. It is time to heed that silence and cease expending time and energy on issues that do not exist.

CONCLUSION

For all of the foregoing reasons, and for all the reasons set forth in defendants' various memoranda in support (Dkt. Nos. 6084, 6161, and 6218) of their Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims (Dkt. No. 6052), this Court should enter summary judgment in defendants' favor with regard to all Medicaid claims reimbursed (or that should have been reimbursed) by New York Medicaid on the basis of a FUL established by CMS (or its predecessor, HCFA).

Respectfully submitted,

/s/ John P. Bueker

John T. Montgomery (BBO# 352220)
John P. Bueker (BBO# 636435)
Kim B. Nemirow (BBO# 663258)

ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Dated: December 9, 2009

CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2009, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ John P. Bueker
John P. Bueker